IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	**Case No. 1:14-cv-1748** **MDL No. 2545** **Hon. Matthew F. Kennelly**
THIS DOCUMENT RELATES TO: All Cases Listed in Exhibit A to Motion	

ACTAVIS, INC.; ACTAVIS PHARMA, INC.; ACTAVIS LABORATORIES UT, INC.; WATSON LABORATORIES, INC.; ANDA, INC.; AUXILIUM PHARMACEUTICALS, INC.; PFIZER INC.; AND PHARMACIA & UPJOHN COMPANY LLC'S MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS AND FOR JUDGMENT ON THE PLEADINGS PURSUANT TO FEDERAL RULES OF CIVIL PROCEDURE 12(b)(6) AND 12(c)

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I. INTRODUCTION

The United States Supreme Court has made clear twice in the past four years that state-law claims involving generic medications are preempted by federal law. *PLIVA, Inc. v. Mensing*, 564 U.S. ---, 131 S. Ct. 2567, 2572, *reh'g denied*, 132 S. Ct. 55 (2011); *Mutual Pharm. Co. v. Bartlett*, 570 U.S. ---, 133 S. Ct. 2466, 2470 (2013). In *Mensing*, the Court held that state-law failure-to-warn claims are preempted because a company selling a generic medication cannot change the label without approval of the federal Food and Drug Administration ("FDA"). *Mensing*, 131 S. Ct. at 2577-78. In *Bartlett*, the Court held that state-law design defect claims targeting generic pharmaceutical products also are preempted and rejected the argument that a generic drug manufacturer can be forced to stop selling its product to avoid state-law liability. *Bartlett*, 133 S. Ct. at 2477. Together, the Supreme Court's decisions in *Mensing* and *Bartlett* "establish that under the [Federal Food, Drug, and Cosmetic Act ("FDCA")] a generic [drug company] may not unilaterally [1] change its labeling or [2] change its design or formulation, and cannot be required to [3] exit the market or [4] accept state tort liability. Therefore, if a generic drug manufacturer cannot satisfy a state law duty except by taking one of these four actions, that law is preempted and of no effect." *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 476 (4th Cir. 2014).

Here, defendants Actavis Pharma, Inc.; Actavis Laboratories UT, Inc.; Anda, Inc.; Actavis, Inc.; Watson Laboratories, Inc., a Nevada corporation (the "Actavis Defendants");[1] Pfizer Inc., and Pharmacia & Upjohn Company, LLC (the "Pfizer Defendants"); and Auxilium Pharmaceuticals, Inc., (collectively "ANDA Defendants") hold abbreviated new drug applications ("ANDAs") for generic testosterone replacement therapy ("TRT") products, which

[1] Defendants Actavis, Inc., and Watson Laboratories, Inc., a Nevada corporation, do not possess ANDAs for generic TRT products and do not manufacture, sell, or distribute ANDA TRT products; they have been named in complaints mistakenly, or have been named as parent, subsidiary, or affiliated companies of other named defendants.

are the subject of the claims asserted in plaintiffs' Master Long-Form Complaint ("Master Complaint") and individual complaints alleging injuries from exposure to ANDA TRT products. The Master Complaint includes ten claims for relief asserted against all defendants, captioned as strict liability – design defect (First Claim for Relief); strict liability – failure-to-warn (Second Claim for Relief); negligence (Third Claim for Relief); negligent misrepresentation (Fourth Claim for Relief); breach of implied warranty of merchantability (Fifth Claim for Relief); breach of express warranty (Sixth Claim for Relief); fraud (Seventh Claim for Relief); redhibition (Eighth Claim for Relief); violation of various consumer protection statutes (Ninth Claim for Relief); and unjust enrichment (Tenth Claim for Relief). (*See generally* Master Complaint, Doc. 705.) Those claims are premised on three sets of allegations: (1) Defendants wrongly promoted their ANDA TRT products for off-label uses (*id.*, ¶¶ 102-385); (2) defendants inadequately warned about the risks and dangers of their ANDA TRT products (*id.*, ¶¶ 386-429); and (3) defendants defrauded FDA by intentionally withholding information from FDA in an effort to get their ANDA TRT products approved (*id.*, ¶¶ 430-465).

Regardless of the title given or the premise of the cause of action, however, one conclusion is certain – the claims are preempted by federal law. That is so because under each alleged claim, ANDA Defendants could escape state-law liability only by changing their products' design, changing their products' warnings, or leaving the marketplace to avoid the potential imposition of state-law damages. Because the ANDA Defendants cannot unilaterally change their products' design or warnings under federal law and cannot be forced to leave the market or accept state tort liability under the Supreme Court's impossibility preemption jurisprudence, all plaintiffs' claims against ANDA Defendants are preempted, and their lawsuits must be dismissed.

With regard to plaintiffs' allegations involving fraud on FDA and off-label promotion, the Supreme Court has been equally clear that state-law claims that seek redress for allegedly fraudulent statements made to FDA are preempted by federal law, because they are based exclusively on federal regulations and interfere with the FDA's power to police the federal scheme created by Congress. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). For that same reason, courts applying *Buckman*—as well as *Mensing* and *Bartlett*—have held that claims alleging that defendants engaged in off-label promotion also are preempted.

Finally, ANDA Defendants' motion presents a pure issue of law regarding the application of *Mensing* and *Bartlett* to the claims asserted against them. The only conceivable factual issue—whether FDA approved the ANDA Defendants' medications pursuant to ANDAs—is one of which the Court can take judicial notice and on which plaintiffs need no discovery, contrary to plaintiffs' pre-motion arguments. Accordingly, the ANDA Defendants respectfully request that the Court grant their motion and dismiss all claims against them relating to their ANDA medications.

II. BACKGROUND

A. FDA'S REGULATION OF GENERIC PHARMACEUTICAL PRODUCTS

In 1938, Congress passed the FDCA. Under the statute, a drug could not be marketed without the submission of a new drug application ("NDA") establishing that the drug was safe. *See* 21 U.S.C. § 301 *et seq.* The FDCA originally provided that an NDA automatically became effective unless FDA affirmatively refused to approve the application within a fixed period of time. *See Abbreviated New Drug Application Regulations – Final Rule* ("ANDA Regs"), 57 Fed. Reg. 17950 (April 28, 1992) (codified at 21 C.F.R. Part 314). In 1962, Congress amended the FDCA to require affirmative approval by FDA of all new drug applications before they were marketed. *See* Public Law 87-781, Oct. 10, 1962. The 1962 amendments also required

applicants to show that their products were not only safe but also effective. *See id.*; *see also* ANDA Regs, 57 Fed. Reg. 17950.

Following the 1962 amendments, FDA also began systematically evaluating whether there was substantial evidence of effectiveness for those drugs that FDA previously approved or that were deemed approved before the amendments. *See* ANDA Regs, 57 Fed. Reg. 17950. That program became known as the Drug Efficacy Study Implementation ("DESI") process. *See id.* Under DESI, FDA published notices in the Federal Register containing acceptable marketing conditions, including required labeling, for the class of drug products covered by the notice. *See id*. For example, in 1970, FDA published a DESI notice finding that certain androgens, including testosterones for subcutaneous implantation and intramuscular injection, were effective for certain indications. *See Certain Androgen Preparations, Drugs for Human Use; Drug Efficacy Study Implementation*, 35 Fed. Reg. 12356 (August 1, 1970).

Shortly after the 1962 amendments, FDA also created an abbreviated procedure for the approval of drugs that were identical, similar, or related to those approved before 1962 and subject to FDA's DESI evaluations. *See* ANDA Regs, 57 Fed. Reg. 17950. Under that procedure, FDA published a notice in the Federal Register announcing its conclusion that a particular drug was effective and suitable for others to seek approval through abbreviated applications. *See id., citing New Drugs, Abbreviated Applications*, 34 Fed. Reg. 2673 (Feb. 27, 1969); *Approval of Certain New-Drug Applications and Supplements*, 35 Fed. Reg. 6574 (Apr. 24, 1970); *Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study, Drugs for Human Use; Drug Efficacy Study Implementation*, 35 Fed. Reg. 11273 (July 14, 1970). The abbreviated procedures for "duplicate" drugs based on DESI notices applied to medications that were "the same in active ingredient, dosage form and strength, route of administration, and conditions of use as the drug product that was the subject of the finding." *Abbreviated New*

Drug Applications; Related Drug Amendments – Final Rule, 48 Fed. Reg. 2751, 2753, 2755 (Jan. 21, 1983) ("FDA's Abbreviated Application Regs"). A manufacturer of a "duplicate" drug also was required to include labeling that was "in accord with the labeling conditions described in the finding that an abbreviated new-drug application [was] sufficient." 21 C.F.R. § 314.2 (1984); *see also Approval of Certain New-Drug Applications and Supplements*, 35 Fed. Reg. 6574, 6575 (April 24, 1970). In other words, the labeling accompanying an abbreviated application before 1984 had to be the same as the labeling included in the DESI notice finding efficacy for that particular drug. *See* FDA's Abbreviated Application Regs, 48 Fed. Reg. 2756.

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act (also known as the Hatch-Waxman Amendments to the FDCA), which codified the abbreviated application procedures used by FDA for duplicate versions of new drugs originally approved before 1962 and applied those procedures to duplicate versions of new drugs approved after 1962 as well. *See* Pub. Law 98-417, 98 Stat. 1585, Secs. 101, 102 (1984) (codified at 21 U.S.C. § 355). Under those procedures, as before, a company filing an ANDA had to show that: (1) the conditions of use described in the labeling for the ANDA drug have been previously approved; (2) the active ingredient for the ANDA drug is the same as the previously approved drug; (3) the route of administration, dosage form, and strength are the same; (4) the ANDA drug is bioequivalent to the previously approved drug; and (5) the labeling for the ANDA drug is the same as the labeling approved for the previously approved drug. *See* 21 U.S.C. § 355(j)(2)(A)(i)-(v). In the amendments, Congress also explicitly provided that FDA's existing abbreviated application regulations would apply to all abbreviated new drug applications until such time as FDA promulgated regulations to implement Hatch-Waxman, *id.*, Sec. 105, which

FDA proposed in 1989 and finalized in 1992.[2] *Abbreviated New Drug Application Regulations – Proposed Rule*, 54 Fed. Reg. 28872, 28884 (July 10, 1989); ANDA Regs, 57 Fed. Reg. at 17950.

When it published the final regulations, FDA rescinded its pre-Hatch-Waxman abbreviated application regulations and made clear that the new regulations applied to all medications approved pursuant to an ANDA—whether approved before or after 1984. *See* ANDA Regs, 57 Fed. Reg. 17981, 17983; *see also* 57 Fed. Reg. 17956 (rejecting comment that FDA preclude ANDAs under Hatch-Waxman for DESI drugs and stating: "The ANDA provisions of the 1984 amendments are applicable to all generic drugs for which approval is sought after September 24, 1984, the date on which the statute was enacted. Perpetuating different ANDA systems for pre-1962 drugs and post-1962 drugs would be needlessly confusing, illogical, and inefficient to FDA, the public, and industry. Therefore FDA has included DESI drugs in these regulations."); 21 C.F.R. § 314.3 (1993) (defining "abbreviated application" to include all applications described in 21 C.F.R. § 314.94, including all amendments and supplements). Under the FDCA and FDA's regulations promulgated to implement the Hatch-Waxman amendments, generic pharmaceutical companies are not free to change either the product's design or labeling following approval. *See* 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. § 314.94(a); *Mensing*, 131 S. Ct. at 2574-75; *Bartlett*, 133 S. Ct. at 2470-71.

[2] As part of its implementation of the Hatch-Waxman Amendments, FDA formalized its list of "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the Orange Book), in which FDA designates certain medications as the "reference listed drug" (or "RLD") for each compound and dose. *See* 21 C.F.R. § 314.3 (2015); http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#RLD. Generally, the RLD is the brand-name or innovator drug approved under an NDA, though occasionally where the NDA drug is no longer marketed, FDA determines the "market leader" on the basis of commercial data. ANDA Regs, 57 Fed. Reg. 17958. An ANDA applicant must show that its proposed medication is bioequivalent to the RLD and that it will use labeling that is in all pertinent respects "'the same as' the labeling approved" for the RLD. *Mensing*, 131 S. Ct. at 2574 (quoting 21 U.S.C. § 355(j)(2)(A)(v) and citing *id.* § 355(j)(4)(G)). Where FDA has designated an ANDA medication as the RLD, however, the ANDA seller still cannot change the label unilaterally and continues to be regulated as the generic medication it is, such that impossibility preemption still applies. *See In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 933 (6th Cir. 2014) ("Every federal court to consider this issue has held that FDA's designation of a generic manufacturer's drug as the RLD does not subject an ANDA product to NDA, or brand-name, status or requirements." (citing *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777-78 (5th Cir. 2013)); *Moore v. Mylan Inc.*, 840 F. Supp. 2d 1337, 1348 (N.D. Ga. 2012); and *Cooper v. Wyeth, Inc.*, No. 09-cv-929-JJB, 2012 WL 733846, *9 (M.D. La. Mar. 6, 2012))).

B. ANDA DEFENDANTS AND THEIR TRT PRODUCTS

FDA approved each TRT at issue here through the ANDA process. (*See* ANDA Defendants' request for judicial notice ("RJN"), ¶ 2, Exs. 1-5.) All defendants' products remain on the market today.

- In 1972, FDA approved an ANDA filed by Bartor Pharmacal Company, Inc., a predecessor to Auxilium, for Testopel®, a testosterone pellet implanted subcutaneously.
- In 1978, FDA approved an ANDA filed by Watson Laboratories (now known as Actavis Laboratories UT, Inc.) for 100 mg/ml injections of testosterone cypionate.
- In 1979, FDA approved an ANDA filed by Pharmacia & Upjohn for various doses of Depo-Testosterone®, also an injectable testosterone cypionate.
- In 1980, FDA approved an ANDA filed by Watson Laboratories for injectable testosterone enanthate.
- In 1981, FDA approved an ANDA filed by Watson for a 200 mg/ml injectable dose of testosterone cypionate.
- Between 2005 and 2013, FDA also approved a number of subsequent ANDAs for injectable testosterone cypionate and testosterone enanthate.

C. PLAINTIFFS' ALLEGATIONS

On March 17, 2015, plaintiffs filed their Master Complaint alleging personal injuries from their alleged use of "nine different [TRT] products manufactured[,] sold, distributed, and promoted by six sets of defendants ...." (Master Complaint, ¶ 1.) The TRTs at issue consist of both ANDA TRTs and NDA TRTs. (*Id.*, ¶ 6.) The ANDA Defendants are manufacturers or sellers of ANDA TRTs or affiliated companies of those manufacturers or sellers. (*Id.*, ¶¶ 39-44, 45-48, and 49-56.)

Plaintiffs allege that TRTs cause a number of adverse cardiovascular events, such as heart attacks, strokes, and venous thromboembolic events (such as deep vein thrombosis and pulmonary embolism), of which defendants allegedly failed to warn. (*See, e.g.*, *id.*, ¶¶ 11, 392, 395; *see generally id.*, ¶¶ 386-429.) Plaintiffs also allege that defendants wrongly marketed and

promoted their TRTs for off-label uses (*id.*, ¶¶ 102-385), and defrauded FDA by intentionally withholding information from FDA in an effort to secure approval of their ANDA TRTs. (*Id.*, ¶¶ 430-465.) Plaintiffs assert ten primary claims[3] for relief against all defendants based on those allegations. (*See id.*, ¶¶ 470-632.) Yet, each cause of action, regardless of its title, revolves around an alleged failure to warn.

- "Nature of the Action": Plaintiffs allege that defendants' TRTs "cause serious medical problems, including life threatening cardiac, cerebrovascular, and thromboembolic events, for which ***Defendants failed to provide adequate warnings***." (*Id.*, ¶ 5 (emphasis added).)

- "Facts Common to All Claims": Plaintiffs allege defendants "***failed to provide adequate warnings*** of the dangerous effects of [TRT], so that prescribers and consumers were misinformed about both the risks and the benefits of TRTs." (*Id.*, ¶ 101 (emphasis added).)

- "Facts Common to All Claims": Plaintiffs allege the "package materials of each of the Defendants' TRT products ***did not adequately warn*** against stroke, pulmonary embolism, transient ischemic attack, cardiovascular disease, myocardial infarction, coronary heart failure, or any thromboembolic event not related to polycythemia." (*Id.*, ¶ 395 (emphasis added).)

- "Facts Common to All Claims": Plaintiffs allege "[t]o the extent that any dangers of [or] resulting from [TRTs] were not known at the time any of the products were brought to market, the Defendants, and each of them, were entitled, and required, to make unilateral ***changes to the labels for their products in order to warn*** physicians and consumers of dangers of which they became aware." (*Id.*, ¶ 406 (emphasis added).)

- "First Claim for Relief – Strict Liability – Design Defect": Plaintiffs allege defendants had "knowledge of the safety and efficacy problems and suppressed this knowledge from the general public and "made ***conscious decisions not to redesign, re-label, warn or inform*** the unsuspected [sic] public." (*Id.*, ¶ 478 (emphasis added).)

- "Second Claim for Relief – Strict Liability – Failure-to-Warn": Plaintiffs allege "[t]he TRT products manufactured and/or supplied by Defendants [were] defective due to ***inadequate warnings or instructions*** because Defendants knew or should have known that the product[s] created significant risks of serious

[3] The Master Complaint also includes four "claims"—wrongful death, survival action, loss of consortium, and punitive damages—that are not independent torts. The loss of consortium claim is derivative and only would apply in cases where the TRT user prevails on at least one of the primary claims. (*See id.*, ¶¶ 633-657.)

bodily harm to consumers, and they ***failed to adequately warn*** consumers and/or their health care providers of such risks." (*Id.*, ¶ 482 (emphasis added).)

- "Third Claim for Relief – Negligence": Plaintiffs allege defendants "had a duty to disclose to physicians and healthcare providers the causal relationship or association of TRT products to heart attack, stroke, deep vein thrombosis and its sequelae, pulmonary embolism, and sudden cardiac death," but breached that duty by "***failing to adequately test and warn*** of the risks and dangers of TRT." (*Id.*, ¶¶ 495, 497 (emphasis added).)

- "Fourth Claim for Relief – Negligent Misrepresentation": Plaintiffs allege defendants "willfully deceived Plaintiffs, Plaintiffs' physicians and the general public as to the health risks and consequences of the use of the TRT products," despite having "a duty to provide Plaintiffs, physicians and other consumers with ***true and accurate information and warnings*** of any known risks and harmful side effects of the drugs they marketed, distributed and sold." (*Id.*, ¶¶ 511, 512 (emphasis added).)

- "Fifth Claim for Relief – Breach of Implied Warranty of Merchantability": Plaintiffs allege ***defendants warranted their products were safe and fit*** but were not "minimally safe for their expected purpose." (*Id.*, ¶¶ 523, 524.)

- "Sixth Claim for Relief – Breach of Express Warranty": Plaintiffs allege defendants' TRT products ***did not conform to representations defendants made, inter alia, in their package inserts***. (*Id.*, ¶¶ 533, 537.)

- "Seventh Claim for Relief – Fraud": Plaintiffs allege defendants "conceal[ed]" "the true facts concerning TRT products"; that consumers would not have used TRT products if they had been "provided with adequate, true, accurate, and correct information by Defendants about the risks of cardiovascular events and cerebrovascular accident causally associated with the use of TRT products"; and that ***defendants did not "warn[]" of purported potential risks*** associated with TRT use. (*Id.*, ¶¶ 546, 557, 559.)

- "Eighth Claim for Relief – Redhibition": Plaintiffs allege TRTs are ***defective and unreasonably dangerous "as described above,"*** which incorporates the general allegations of the complaint alleging inadequate warnings. (*Id.*, ¶¶ 567, 568.)

- "Ninth Claim for Relief – Consumer Protection": Plaintiffs allege defendants violated consumer protection laws "when ***they failed to adequately warn*** … of the safety risks associated with TRT products." (*Id.*, ¶¶ 573, 623 (emphasis added).)

- "Tenth Claim for Relief – Unjust Enrichment": Plaintiffs allege defendants were unjustly enriched as a result of their "wrongdoing" as set forth in the Complaint. (*Id.*, ¶ 629.)

The Master Complaint, however, is devoid of allegations that the cardiovascular risks defendants allegedly failed to disclose—and plaintiffs' resulting injuries—differ in any manner based on whether plaintiffs used an ANDA Defendant's TRT for approved or alleged off-label uses.

III. LAW AND ARGUMENT

A. PLAINTIFFS' CLAIMS ARE PREEMPTED AS HELD IN *MENSING* AND *BARTLETT*

1. Plaintiffs' Failure-to-Warn Based Claims Are Preempted

In *Mensing*, and again in *Bartlett*, the United States Supreme Court found that federal law governing ANDA medications preempts state-law tort claims targeting those products. *See Mensing*, 131 S. Ct. at 2577; *Bartlett*, 133 S. Ct. at 2473.[4] The Court noted that a company selling an ANDA medication cannot change its label unilaterally without FDA's permission. *See Mensing*, 131 S. Ct. at 2575 (finding "changes unilaterally made to strengthen a generic drug's warning label would violate the statutes and regulations requiring a generic drug's label to match its brand-name counterpart's"). The Court reasoned that because the state law duties imposed would require companies that sell generic medications to violate federal law to escape liability under state law, it is impossible for the companies to comply with both. Under the Supremacy Clause of the United States Constitution, federal law trumps state law, and state law failure-to-warn claims are therefore preempted. *See Bartlett*, 133 S. Ct. at 2476-77; *Mensing*, 131 S. Ct. at 2577-78.[5]

[4] In *Mensing*, the Supreme Court uses the term "generic" to refer to ANDA medications and "branded" to refer to NDA medications, although an ANDA holder could use a proprietary or "brand" name to refer to one of its ANDA medications (such as the Pfizer Defendants' use of the brand name Depo-Testosterone® or Auxilium's use of the brand name Testopel®) to distinguish it from an ANDA medication manufactured by another company.

[5] In *Mensing*, the plaintiff asserted fourteen separate causes of action, including strict liability failure-to-warn, negligent failure-to-warn, breach of express and implied warranties, misrepresentation, fraud, unfair trade practices, false advertising, and consumer fraud. The district court found "all of Plaintiff's claims are essentially 'failure to warn' claims and are encompassed by the Court's preemption analysis." *Mensing v. Wyeth*, Inc., 562 F. Supp. 2d 1056, 1061 n.6 (D. Minn. 2008), *rev'd* 588 F.3d 603 (8th Cir. 2009), *rev'd sub nom. PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), *and opinion vacated in part, reinstated in part*, 658 F.3d 867 (8th Cir. 2011).

In *Mensing*, the Court viewed preemption broadly and rejected plaintiffs' attempts to limit its scope. For example, the Court held that the sameness requirement applies after approval as well as before, holding that companies that sell generic medications cannot deviate their product labeling after approval because it must be the "same as" the labeling of the drug product on which the ANDA was based. *Mensing*, 131 S. Ct. at 2575-76. The Court also interpreted the scope of labeling broadly; it rejected the plaintiffs' arguments that the defendants could have sent "Dear Doctor letters" warning healthcare professionals about certain risks. The Court observed that such "letters qualify as 'labeling'" subject to the sameness requirement, *id.* at 2576 (citing 21 C.F.R. § 202.1(l)(2) & 21 U.S.C. § 321(m)), and further emphasized that "if generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'" *Mensing*, 131 S. Ct. at 2576.

Finally, the Court did not require companies to "take[] steps" to change the product labeling by alerting FDA to the need for stronger warnings. *Id.* at 2579-82. Even though federal law did not prohibit the companies from sharing such information with FDA—and indeed, even though the Solicitor General's brief asserted that federal law *required* the companies to do so—the Court declared that sharing such information with FDA would not have remedied the allegedly defective product warnings giving rise to the plaintiffs' claims because it depended on authorization and action by FDA. *Id*. at 2581 ("[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance … that party cannot independently satisfy those state duties for pre-emption purposes."). The Court held that the plaintiffs' lawsuits were preempted in their entirety: "[B]ecause pharmacists, acting in full accord with state law, substituted generic metoclopramide [for brand-name Reglan®], instead

federal law pre-empts these lawsuits. We acknowledge the unfortunate hand that federal drug regulation has dealt Mensing, Demahy, *and others similarly situated*." *Id*. (emphases added).

In *Bartlett*, the Court reiterated its holding in *Mensing* and expressly rejected the plaintiff's arguments that her claim was not preempted because the generic drug manufacturer defendant could have "pulled [the product] from the market" to avoid state-law liability. *Bartlett*, 133 S. Ct. at 2470, 2475, 2477-78. As in *Mensing*, the Court held that the plaintiff's claims were preempted by federal law.

In short, because federal law prohibits sellers of generic medications from unilaterally changing their product labels and because the companies cannot be required to exit the market or accept state-law tort liability, any state-law cause of action is preempted and of no effect if the companies can satisfy their state-law duty only through one of those avenues. *Drager*, 741 F.3d at 476. Indeed, in the wake of *Mensing*, many courts of appeals and district courts have found that failure-to-warn claims against ANDA sellers are preempted.[6] This Court should do the same, and find that plaintiffs' claims for relief based on defendants' alleged failure to warn are preempted.

2. Plaintiffs' Design Defect Based Claims Are Preempted

Plaintiffs' design defect claims also fail, for two reasons. First, the Master Complaint merely includes rote allegations such as "the design was defective and unsafe in that [it] caused serious injuries and death" and "the design defect made these drugs unreasonably dangerous." (Master Complaint, ¶¶ 473, 475.) Those allegations do not satisfy plaintiffs' pleading requirements under *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), and *Bell Atl. Corp v. Twombly*,

[6] *See, e.g.*, *Drager*, 741 F.3d at 476; *Eckhardt v. Qualitest Pharm., Inc.*, 751 F.3d 674, 677-81 (5th Cir. 2014); *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1137-39 (8th Cir. 2014); *Moretti v. Wyeth, Inc.*, 579 Fed. Appx. 563, 565-66 (9th Cir. 2014); *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 390-98 (6th Cir. 2013); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1286-88 (10th Cir. 2013); *Guarino v. Wyeth LLC*, 719 F.3d 1245, 1249-50 (11th Cir. 2013); *Dolin v. Smithkline Beecham Corp.*, No. 12 C 6403, --- F. Supp. 3d ----, 2014 WL 804458, at *13 (N.D. Ill. Feb. 28, 2014); *Wagner v. Pfizer, Inc.*, No. 13-cv-497-jdp, 2014 WL 3447476, at *3 (W.D. Wis. July 11, 2014).

550 U.S. 544, 570 (2008). *See, e.g., Purvis v. Teva Pharms. USA, Inc.*, 901 F. Supp. 2d 716, 721 (M.D. La. 2012); *Fullington v. PLIVA, Inc.*, No. 4:10-cv-236, 2011 WL 6153608, at *5 (E.D. Ark. Dec. 12, 2011).

Second, any design defect claim asserted against the ANDA Defendants' ANDA TRTs is preempted. *See Bartlett*, 133 S. Ct. at 2466. As the Court recognized in *Bartlett*, a company selling an ANDA medication cannot change the product's design. As is true of sulindac (the generic medication at issue in *Bartlett*), TRT products cannot be changed factually (*i.e.*, chemically the composition cannot be changed) or legally (*i.e.*, federal law requires an ANDA medication to have the same active ingredients, route of administration, dosage form, and strength as the RLD). As a result, a manufacturer cannot comply simultaneously with federal law—which prohibits changes to an ANDA medication's design—and a state-law tort claim seeking to impose a duty to change the design of the medication. *Bartlett*, 133 S. Ct. at 2475.

Nor was the Court persuaded that an ANDA seller should evade liability under state law by exiting the market. In fact, the Court flatly rejected the "stop selling" argument because "the Court of Appeals' stop-selling rationale would render impossibility pre-emption a dead letter and work a revolution in this Court's pre-emption case law." *Bartlett*, 133 S. Ct. at 2470; *see id.* at 2477 (noting "stop selling" theory is "incompatible" with preemption jurisprudence, which presumes "that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability"). Again, where "federal law forbids an action that state law requires, the state law is 'without effect.'" *Id.* at 2476-77.

Because ANDA Defendants can neither re-design their ANDA TRT products, nor change the labeling of those ANDA TRT products, they cannot be held liable under any state-law design defect theory. *Id*. at 2475-77; *Mensing*, 131 S. Ct. at 2575-77. In light of the Supreme Court's decisions, this Court should dismiss plaintiffs' design defect claims.

3. *Mensing* and *Bartlett* Foreclose Plaintiffs' Negligence, Breach of Warranty, Negligent Misrepresentation, Fraud, Redhibition, Consumer Protection, and Unjust Enrichment Claims for Relief

Plaintiffs' other claims for relief also must be dismissed for either of two reasons. First, even though those claims have various captions, they are in substance failure-to-warn and/or design defect claims that are preempted under *Mensing* and *Bartlett*. Second, the duties plaintiffs seek to impose under their various claims would leave the ANDA Defendants with no way to comply simultaneously with federal and state law, and are preempted for that reason as well.

Throughout their Master Complaint, plaintiffs assert they were injured by the ANDA Defendants' alleged failure to warn about cardiovascular and other safety risks. Courts "have interpreted *Mensing* to broadly preempt claims that are, at their core, claims that the generic manufacturer failed to provide additional warnings beyond that which was required by federal law of the brand-name manufacturers." *Strayhorn*, 737 F.3d at 391-92 (affirming dismissal of breach of express and implied warranty claims); *see also, e.g.*, *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.*, 756 F.3d at 935-36 (affirming dismissal of express warranty, implied warranty, fraud, misrepresentation, consumer protection, unjust enrichment, and other derivative claims); *Schrock*, 727 F.3d at 1287-90 (affirming dismissal of breach of warranty claims); *Guarino*, 719 F.3d at 1249 ("Guarino's attempt to elude *Mensing* by clothing her allegations as 'failure-to-communicate' claims rather than failure-to-warn claims does not alter our analysis. No matter the garb in which she attempts to present them, Guarino's claims are at bottom allegations regarding Teva's failure to warn her of the dangers of long-term metoclopramide use, and they therefore cannot escape *Mensing's* grasp."); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1095-96 (8th Cir. 2013) (finding negligence and misrepresentation claims were

preempted).[7] The same holds true here, as every one of plaintiffs' claims against the ANDA Defendants is premised on those defendants' alleged failure to warn about the cardiovascular risk of their TRTs. To the extent those claims seek damages for personal injuries based on an alleged failure to warn, they are preempted, and the Court should dismiss them.[8]

Second, the claims should be dismissed because under *Mensing* and *Bartlett*, an avenue must exist through which an actor can satisfy its state-law duty and avoid liability without running afoul of federal law or being forced to exit the market. All plaintiffs' claims for relief ask the ANDA Defendants to do one or both of the following to avoid liability: (1) change the design of their ANDA TRT products; or (2) change the products' labeling. In each instance, state tort liability could be avoided only by instituting a change that is prohibited by federal law or is impossible under the laws of science.

Plaintiffs' breach of implied warranty of merchantability claim is a prime example. Plaintiffs allege ANDA Defendants can be held liable under a breach of implied warranty theory because state law requires that the ANDA TRT products they sell be merchantable and safe for their intended use. (Master Complaint, ¶¶ 522-531.) The allegations that the ANDA TRT products are not merchantable are no more than assertions that the designs should be different, or

[7] Similarly, many district courts have found claims like plaintiffs assert here preempted. *See, e.g.*, *Rojas v. Teva Pharms., USA, Inc.*, 920 F. Supp. 2d 772, 779-82 (S.D. Tex. 2013) (failure to withdraw, design defect, off-label promotion, and implied warranty claims preempted); *Gardley-Starks v. Pfizer, Inc.*, 917 F. Supp. 2d 597, 608-11 (N.D. Miss. 2013) (failure-to-withdraw, failure to communicate, failure to conduct post-marketing surveillance and reporting, failure to update, and defective design claims preempted); *Moretti v. Mutual Pharm. Co.*, 852 F. Supp. 2d 1114, 1117-19 (D. Minn. 2010) (failure to communicate, failure to conduct and report data, and failure to remove product from market all based on failure to warn and preempted), *aff'd*, 518 Fed. Appx. 486 (8th Cr. 2013); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 658-59 (D. Md. 2011) (negligence for continuing to sell, concealing important safety information, and failing to test preempted), *aff'd Drager*, 741 F.3d 470.

[8] There is a difference between the preemption analysis required by this motion and the pleading requirements this Court considered in denying earlier motions to dismiss personal injury complaints that pre-dated the Master Complaint. As such, this Court's previous finding that "[t]he fraud and negligent misrepresentation claims are . . . distinct from the failure to warn claims," *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 14 C 1748, 2014 WL 7365872, at *7 (N.D. Ill. Dec. 23, 2014), is not determinative of the preemption question and the conclusion reached by the Sixth, Eighth, Tenth, and Eleventh Circuits that such claims are preempted.

that the warnings and labeling should be different.[9] *See, e.g., Schrock*, 727 F.3d at 1288-89 (finding breach of warranty claim properly characterized as failure-to-warn claim or design defect claim, which are preempted). Yet, ANDA Defendants cannot change the design or the labeling of their TRTs to avoid liability. The only other action an ANDA Defendant could take to avoid liability is to stop selling ANDA TRT products, which the *Bartlett* Court flatly rejected. *See Bartlett*, 133 S. Ct. at 2470.

The same analysis applies to each of plaintiffs' claims for relief. In each instance, the claim would require ANDA Defendants to either change product labeling, change product design, exit the market or pay damages.[10] The first two avenues are prohibited under federal law and the last two are not required and cannot form the basis for evading preemption of the state-law claims. As a result, all plaintiffs' claims for relief must be dismissed.

B. PLAINTIFFS' "OFF-LABEL" MARKETING AND PROMOTION ALLEGATIONS DO NOT SAVE THEIR CLAIMS

Plaintiffs' allegations regarding the ANDA Defendants' alleged promotion of their ANDA TRTs for "off-label" uses do not save their claims for at least three reasons. First, the allegations are inadequately pled. Second, the allegations do not change the preemption analysis. Third, the claims are prohibited attempts to enforce the provisions of the FDCA.

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[9] Plaintiffs have not pled any facts supporting any manufacturing defect in the ANDA TRT products.

[10] Plaintiffs' breach of express warranty claim, like their breach of implied warranty claim, alleges that ANDA Defendants represented their products were safe and effective for their intended use. (Master Complaint, ¶¶532-42.) That claim merely challenges the content of the product descriptions for TRT products based on defendants' alleged duty to make true statements about safety and efficacy in their labels. Because ANDA Defendants cannot change their written materials or the formulation of their TRT products to ensure they function as expressly warranted, ANDA Defendants can avoid liability for breach of express warranty only by leaving the market. As they are not required to exit the market to avoid liability, plaintiffs' breach of express warranty claims are preempted. *See, e.g., Drager*, 741 F.3d at 479 (holding express warranty claim preempted).

Plaintiffs' negligent misrepresentation and fraud claims likewise are premised on allegedly false and misleading representations regarding the safety of TRT products based on defendants' alleged duty to make true statements about the safety of their TRT products in their labels and other written material. The same is true of plaintiffs' claims for redhibition, violation of consumer protection statutes, and unjust enrichment; i.e., they all are premised on allegedly misleading or untruthful statements or representations and defendants' alleged duty to make certain statements regarding their TRT products. In each instance, ANDA Defendants' only recourse to avoid liability is to change product labeling or design or cease sales of the products. The first two are prohibited and the last is not required.

1. Plaintiffs' Off-Label Marketing and Promotion Allegations Are Inadequately Pled Against the Actavis Defendants

A Rule 12(b)(6) or 12(c) motion should be granted when, viewing the allegations in the complaint as true, including all inferences that reasonably may be drawn from the facts alleged, the complaint fails to state a claim upon which relief may be granted. *See Virnich v. Vorwald*, 664 F.3d 206, 212 (7th Cir. 2012). Although the court should accept as true all well-pleaded allegations and should view the complaint in a light most favorable to the plaintiff, the "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555.

As an initial matter, plaintiffs' off-label allegations against the Actavis Defendants are inadequately pled.[11] Plaintiffs say nothing in the Master Complaint about the Actavis Defendants promoting their ANDA TRT products for off-label uses or even that they promoted those products at all. Instead, there are general allegations that "Defendants" promoted "TRT products" for "off-label" uses. Plaintiffs' attempt to lump together all defendants (and all products) in an effort to plead their claims is improper. The Actavis Defendants are entitled to information about the specific conduct for which they allegedly are responsible. The Seventh Circuit recognized that requirement of notice pleading in *Bank of America, N.A. v. Knight*, 725 F.3d 815, 818 (7th Cir. 2013). The court explained that "[e]ach defendant is entitled to know what he or she did that is asserted to be wrongful. A complaint based on a theory of collective responsibility must be dismissed." *Id.*

Indeed, if needed in support of a motion for summary judgment, the Actavis Defendants represent that they could submit an affidavit or declaration attesting to the fact they did not engage in promotional activities with respect to their ANDA TRT products. Here, however, that

[11] The off-label promotion allegations against Auxilium and the Pfizer Defendants are likewise scant, but the Master Complaint contains at least some allegations about those defendants.

is unnecessary because the well-pleaded facts do not allow the Court to infer even the mere possibility of misconduct or that the pleader is entitled to any relief with respect to any alleged promotion of ANDA TRT products by the Actavis Defendants. *See Iqbal*, 129 S. Ct. at 1951; Fed. R. Civ. P. 8(a)(2).

2. Plaintiffs' Claims Are Preempted Despite Allegations of Off-Label Promotion

Notwithstanding similar allegations of off-label marketing and promotion, courts have held that plaintiffs' claims are preempted under *Mensing* and *Bartlett*. For example, in *Rojas*, applying *Mensing*, the court dismissed product liability claims against the generic drug company arising from the failure to warn of risks allegedly associated with long-term use of their medicines. *Rojas*, 920 F. Supp. 2d at 778. The court rejected plaintiff's argument that her claims based on alleged off-label promotion survived. As the court explained, "Plaintiff's claimed alleged off-label promotion was for use of metoclopramide for more than twelve weeks," which "is indistinguishable from the failure to warn claims" preempted under *Mensing*. *Id.* at 780.

Similarly, in *Stephens v. Teva Pharms., U.S.A., Inc.*, No. CV-13-J-1357-NE, 2014 WL 7723296 (N.D. Ala. Oct. 1, 2014), the court rejected the plaintiffs' argument that their product liability claims against the generic drug company based on alleged off-label promotion were not subject to preemption under *Mensing* and *Bartlett*. The court held that the plaintiffs' allegation that "'after Defendants knew or should have known of the risk of injury from ... amiodarone, especially in 'off-label' use, Defendants failed to provide adequate and required warnings to physicians, users or consumers' ... states a classic 'failure to warn' claim, despite plaintiff's representations otherwise," and, therefore, was preempted. *Id.* at *4.

Plaintiffs' claims here are no different than those held preempted in *Rojas* and *Stephens*. As in those cases, plaintiffs' allegations of off-label promotion go hand-in-hand with their

allegations that there was a failure to disclose cardiovascular risks. That those allegations are part and parcel of plaintiffs' failure-to-warn claims is amply demonstrated by the fact that not a single one of plaintiffs' substantive claims is based solely on allegations relating to off-label promotion for benefits as distinct from allegations concerning the alleged failure to disclose cardiovascular risks. Instead, plaintiffs' allegations are that defendants failed to warn of cardiovascular risks generally associated with any use of TRTs, including the off-label uses for which defendants allegedly promoted their products.

Moreover, plaintiffs' Master Complaint is devoid of *any* allegations that the cardiovascular risks that the defendants allegedly failed to disclose—and resulting injuries suffered by plaintiffs—differ in any manner based on whether plaintiffs used an ANDA Defendant's TRT for approved or alleged off-label uses. In the end, plaintiffs cannot succeed on any of their claims unless they establish that the ANDA Defendants failed to disclose cardiovascular risks allegedly associated with their ANDA TRT products. Those allegations state classic failure-to-warn claims that are preempted under *Mensing* and *Bartlett*.[12]

3. Plaintiffs' Off-Label Marketing and Promotion Allegations Do Not State a Viable State-Law Claim and Are Improper Attempts to Enforce the Provisions of the FDCA and FDA's Regulations

Setting aside that plaintiffs' off-label marketing and promotion allegations are inadequately pled and, at best, are failure-to-warn claims plaintiffs are attempting to dress in other clothes, the allegations do not state a viable state-law claim, but instead improperly attempt to enforce provisions of the FDCA and FDA's regulations. More specifically, plaintiffs' allegations hinge on their assertion that promoting pharmaceutical products for "off-label use" is

[12] At a minimum, even if plaintiffs' allegations of off-label promotion regarding the benefit of TRTs could be separated from their allegations concerning the failure to disclose cardiovascular risks—which they cannot—each of plaintiffs' claims is preempted to the extent that it is based on an alleged failure to disclose cardiovascular risks. In that event, their off-label promotion claims relating to the benefits of TRTs should be limited to their pecuniary losses from paying for the TRTs—in other words, a refund of the cost of the TRTs, and no more.

illegal and, as a result, defendants breached some unidentified duty under state law in allegedly doing so. However, Congress was clear when it enacted the FDCA that only FDA has authority to enforce its provisions. *See* 21 U.S.C. § 337(a) (providing proceedings for enforcement, or to restrain violations, of the FDCA "shall be by and in the name of the United States"). On that basis, the Supreme Court has held that there is no private right of action to enforce the FDCA, and that any state law claim that depends on the purported violation of a federal requirement for one of its essential elements is therefore preempted. *See Buckman*, 531 U.S. at 349 n.4 ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who [is] authorized to file suit for noncompliance with the [law]." (citing 21 U.S.C. §337(a)).[13] As a result, plaintiffs do not have standing to pursue those claims.

Plaintiffs will, of course, argue that they are not attempting to enforce the FDCA's provisions or FDA's regulations, but their argument will ring hollow. Whether, and to what extent, any promotion of a medication constitutes "off-label promotion" can be gauged only by reference to the drug's approval under federal law. Drugs are approved for specific indications as noted in the approved labeling for the product. FDA determines whether the safety and efficacy data provided by the manufacturer sufficiently establishes that the drug is safe and

[13] Following *Buckman*, numerous courts have dismissed or upheld the dismissal of cases in which plaintiffs have attempted to assert a private right of action based on alleged violations of the FDCA—including for alleged off-label promotion—finding plaintiffs lack standing to enforce those alleged violations. *See, e.g.*, *Turek v. General Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011); *Scott v. Pfizer, Inc.*, 182 Fed. Appx. 312, 315 (5th Cir. 2006) (unpublished opinion) (upholding dismissal of claims alleging violations of FDCA on standing and subject matter jurisdiction grounds because plaintiff failed to show FDCA creates a private cause of action); *Morris v. Wyeth, Inc.*, No. 09-0854, 2012 WL 601455, at *5 (W.D. La. Feb. 23, 2012) (stating "Plaintiffs have no standing to seek a remedy based on Defendants' alleged violation of FDA regulations because the FDCA does not provide a private right of action") *aff'd* 713 F.3d 774 (5th Cir. 2013); *In re: Epogen & Aranesp Off-Label Marketing & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1289-90 (C.D. Calif. 2008) (finding that the "allegations of off-label promotion are, in essence, misbranding claims that should be reviewed by the FDA," and plaintiffs could not attempt to "create indirectly" a private right of action that "the FDCA does not create directly"); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-cv-5774, 2009 WL 2043604, at *9-10 (D.N.J. July 10, 2009) (granting motion to dismiss complaint alleging plaintiffs injured by off-label promotion of drugs because, inter alia, the case was "clearly an impermissible attempt by Plaintiffs to end-run violations of the FDCA for off-label promotion into a private right of action under RICO and [state statutes]."); *In re Neurontin Marketing and Sales Practices Litig.*, 244 F.R.D. 89, 92 n.6 (D. Mass. 2007) (holding no private right of action under FDCA to enforce off-labeling marketing allegations).

effective for use under the conditions prescribed, recommended, or suggested in the product's label. *See* 21 U.S.C. § 355. Without that approval, there would be no "approved uses," and, hence, could not be any "off-label uses." As a result, for plaintiffs to claim that defendants' alleged promotion for "off-label use" constitutes a breach of some duty, plaintiffs only can be referring to TRT's uses as approved by FDA. And, that allegation is no more than a prohibited attempt to enforce the FDCA and FDA's regulations.

C. PLAINTIFFS' "FRAUD-ON-THE-FDA" CLAIMS ARE PREEMPTED

Finally, to the extent plaintiffs attempt to save any of their claims through their "fraud-on-the-FDA" allegations, those efforts are fruitless, as those allegations are squarely preempted by federal law pursuant to the Supreme Court's decision in *Buckman*. As here, the plaintiffs in *Buckman* alleged that the defendant "made fraudulent representations to the [FDA] in the course of obtaining approval to market" the medical device that plaintiffs alleged caused their injuries. *Buckman*, 531 U.S. at 343. The Supreme Court held that such claims are preempted because allowing private plaintiffs to enforce state-law "fraud-on-the-FDA" claims would necessarily undermine "the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350; *see also Link v. Zimmer Holdings, Inc.*, 604 F. Supp. 2d 1174, 1179 (N.D. Ill. 2008) (holding "any allegations that [defendant] committed a fraud on FDA are [] preempted and therefore cannot provide the basis for [plaintiff's] claims"); *McCutcheon v. Zimmer Holdings, Inc.*, 586 F. Supp. 2d 917, 922 (N.D. Ill. 2008) (same). The same is true here, and none of plaintiffs' causes of action—already preempted under *Mensing* and *Bartlett*—can stand alone in light of *Buckman*.

D. THE COURT CAN AND SHOULD DECIDE IMPOSSIBILITY PREEMPTION ON A MOTION TO DISMISS

At the April 21 status conference, plaintiffs represented that they intend to argue "that this is really going to be a motion for summary judgment" and that they "anticipate some sort of

a [Rule] 56(d) response" to this motion. *See* Transcript of Status Conference held on April 21, 2015 at 3-4. As demonstrated above, the ANDA Defendants' motion presents a pure question of law regarding the application of *Mensing* and *Bartlett* to the claims asserted against the ANDA Defendants. The only conceivable factual issue is whether ANDA Defendants' TRT products are indeed generic medications (as distinct from medications approved via an NDA), and the Court can take judicial notice of those facts. *See* RJN ¶ 5. There is no need for discovery. *See*, *e.g.*, *Garza v. Wyeth LLC*, No. 2:12-CV-198, 2015 WL 364286, at *4 (S.D. Tex. Jan. 27, 2015) (dismissing product liability claims against generic manufacturer under *Mensing*/*Bartlett*, and holding that "[t]here is no need for additional discovery under Fed. R. Civ. P. 56(d), (e)" because "[t]he preemption decision is not evidence-based, but is rather a question of law"); *Wilson v. Amneal Pharms., L.L.C.*, No. 1:13-cv-00333-CWD, 2013 WL 6909930, at *4-*7, *12 (D. Idaho Dec. 31, 2013) (dismissing product liability claims against ANDA holder under *Mensing*/*Bartlett*, and holding that "because the Court may judicially notice all six documents [submitted by defendant], the motion for judgment on the pleadings is not converted into a motion for summary judgment, and Wilson's request for discovery under Rule 12(d) and Rule 56(d) lacks support").

If plaintiffs persist in the argument previewed at the April 21 status conference, they should be required to explain specifically what information they supposedly need to respond to this motion.

IV. CONCLUSION

Personal injury claims brought against sellers of generic medications do not and cannot survive in light of the Supreme Court's decisions in *Mensing* and *Bartlett*. Those decisions mandate dismissal of Plaintiffs' Master Complaint and any and all individual complaints that contain allegations and causes of actions with respect to the ANDA Defendants' ANDA-

approved TRTs. Accordingly, the ANDA Defendants respectfully request that this Court dismiss those claims with prejudice.

Date: May 15, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 15, 2015, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ Joseph P. Thomas